

## **Ciguatera Diagnostic Method Study—Consent Form**

### **For use by Physicians Not Associated with the University of Miami/Jackson Memorial Hospital, Miami, Florida**

#### **Background**

The Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia and the United States Food and Drug Administration (FDA) in Dauphin Island, Alabama are doing research to find new tests for ciguatera (*pronounced “si gwah the’ rah”*) fish poisoning in people. Some ocean plants make ciguatera poison. When fish eat the plants, the poison builds up in the fish. If people eat the fish, they get ciguatera poisoning. Now there is no way to test people for ciguatera poisoning.

Your doctor thinks you have ciguatera fish poisoning. We want you be part of our research study to help us find a new test for ciguatera poisoning. The CDC is leading this study. FDA will be testing the blood and urine.

#### **Study Activities**

*If you agree to be part of this study, your doctor will get about four teaspoons of blood and all your urine while he or she treats you for ciguatera.* We will use it to learn more about what poisons cause ciguatera fish poisoning. Your blood and urine will be marked with only a code number to protect your privacy. We will not know who you are and so cannot give you your test results. These tests will not help you because they are research tests and we don’t know if they work. Right now, the best way to find out if you have this poison is to test the fish that made you sick.

We also want to save the leftover blood and urine to see if other tests for these poisons work. Your blood and urine will only be tested for ciguatera poisons and the chemicals your body makes from these poisons. Again, these leftover specimens will be saved using only a number by FDA. You can still be part of this study even if you do not want your urine or blood to be saved.

#### **Benefits**

There are no direct benefits to you for being in the study. You will not have to pay for this new test. We will not pay you for your blood and urine. If we find a good test for ciguatera, you will not get any money from the sale or use of the new test.

#### **Confidentiality**

We might write about what we learn from this study. If we do, we will not use your name or anything that identifies you. All information and specimens we receive will only be identified with a code. We will keep what we find out about your illness and our test results as private as the law allows. Your doctor will keep this consent form for his or her records in a safe place.

#### **Risks**

It might hurt a little to have blood drawn. Afterwards it may bleed or get infected. Nothing special will be done to get urine from you for this study. You will be urinating into a plastic container or bag. You might be uncomfortable doing this. We do not think anyone will get hurt from this study.

#### **Your Rights**

If you want to know more about your rights as part of this study or if you think you have been hurt by this study, please call the CDC Deputy Director for Science’s office at 1-800-584-8814. Please leave your name, phone number and that you are calling about CDC Protocol #3792. Someone will call you back as soon as they can.

You can decide if you will be part of this study. There is no benefit to you to be part of this study. But by being part of this study, you will help us find a test to diagnose ciguatera in people.

You have the right to not be in this study. If you are not in this study, you will still get your normal medical care.

## Consent

- ☐ I will allow my blood and urine to be collected and sent for ciguatera testing.
- ☐ I will allow any leftover blood and urine to be saved for future ciguatera testing.

---

Printed name

---

Signature

---

Date

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept answers, and signed to enroll in the study.

---

Printed name

---

Signature

---

Date

## **Ciguatera Diagnostic Method Study—Consent Form**

### **For use by Physicians Not Associated with the University of Miami/Jackson Memorial Hospital, Miami, Florida**

The Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia and the United States Food and Drug Administration (FDA) in Dauphin Island, Alabama are doing research to find new tests for ciguatera (*pronounced “si gwah the’ rah”*) fish poisoning in people. Some ocean plants make ciguatera poison. When fish eat the plants, the poison builds up in the fish. If people eat the fish, they get ciguatera poisoning. Now there is no way to test people for ciguatera poisoning.

Your doctor thinks you have ciguatera fish poisoning. We want you be part of our research study to help us find a new test for ciguatera poisoning. The CDC is leading this study. FDA will be testing the blood and urine.

#### **Study Activities**

*If you agree to be part of this study, your doctor will get about four teaspoons of blood and all your urine while he or she treats you for ciguatera.* We will use it to learn more about what poisons cause ciguatera fish poisoning. Your blood and urine will be marked with only a code number to protect your privacy. We will not know who you are and so cannot give you your test results. These tests will not help you because they are research tests and we don't know if they work. Right now, the best way to find out if you have this poison is to test the fish that made you sick.

We also want to save the leftover blood and urine to see if other tests for these poisons work. Your blood and urine will only be tested for ciguatera poisons and the chemicals your body makes from these poisons. Again, these leftover specimens will be saved using only a number by FDA. You can still be part of this study even if you do not want your urine or blood to be saved.

#### **Benefits**

There are no direct benefits to you for being in the study. You will not have to pay for this new test. We will not pay you for your blood and urine. If we find a good test for ciguatera, you will not get any money from the sale or use of the new test.

#### **Confidentiality**

We might write about what we learn from this study. If we do, we will not use your name or anything that identifies you. All information and specimens we receive will only be identified with a code. We will keep what we find out about your illness and our test results as private as the law allows. Your doctor will keep this consent form for his or her records in a safe place.

#### **Risks**

It might hurt a little to have blood drawn. Afterwards it may bleed or get infected. Nothing special will be done to get urine from you for this study. You will be urinating into a plastic container or bag. You might be uncomfortable doing this. We do not think anyone will get hurt from this study.

#### **Your Rights**

If you want to know more about your rights as part of this study or if you think you have been hurt by this study, please call the CDC Deputy Director for Science's office at 1-800-584-8814. Please leave your name, phone number and that you are calling about CDC Protocol #3792. Someone will call you back as soon as they can.

You can decide if you will be part of this study. There is no benefit to you to be part of this study. But by being part of this study, you will help us find a test to diagnose ciguatera in people.

You have the right to not be in this study. If you are not in this study, you will still get your normal medical care.

**Consent**

- ☐ I will allow my blood and urine to be collected and sent for ciguatera testing.
- ☐ I will allow any leftover blood and urine to be saved for future ciguatera testing.

---

Printed name

---

Signature

---

Date

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept answers, and signed to enroll in the study.

---

Printed name

---

Signature

---

Date